Kick-off Meetings at the Federal Institute for Drugs and Medical Devices (BfArM)  
Guidance for Applicants (Version 1)

1. Introduction

The Innovation Office at the Federal Institute for Drugs and Medical Devices (BfArM) offers research organisations, small and medium sized enterprises or start-ups with limited regulatory experience a platform for early informal discussion (Kick-off Meeting) on general regulatory and procedural aspects related to the development and approval of medicinal products or medical devices, which are in the remit of the Institute.

It is the objective of a Kick-off Meeting to raise awareness and understanding of general regulatory requirements at a very early stage of development. Furthermore, Kick-off Meetings aim to provide guidance to the applicants regarding the further project planning and to inform about necessary regulatory procedural steps.

This early dialogue helps to reveal questions, challenges and difficulties that may arise with a view to a forthcoming authorisation process. Promising projects with an innovative approach can be supported effectively by the BfArM at a very early stage of development.

In addition to this, a Kick-off Meeting can also help to prepare for a Scientific Advice by early identification of critical issues.

The following summarises the main information and prerequisites for application of a Kick-off Meeting through the Innovation Office:
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<th><strong>Kick-off Meeting</strong></th>
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| **Addressees**       | ☐ (academic) research organisations  
☐ hospital units  
☐ small- and medium sized enterprises (“SME”); Start-ups |
| **Prerequisites**    | ☐ new active substance/new technology (e.g. new mechanism of action, new technology, high clinical impact)  
☐ early development stage (prior to start of clinical trials )  
☐ no previous completed or requested advice procedure for this product through BfArM/EMA |
| **Objective**        | • Early dialogue between BfArM and (academic) research organisations/“SME”/Start-ups  
• Common identification of regulatory relevant questions and critical topics  
• Feedback on missing data/procedural steps/supporting tools  
• Reference to relevant guidance documents  
• Preparation of a Scientific Advice meeting |
| **Meeting Structure**| Face to face meeting;  
Informal project presentation by the applicant followed by an open scientific discussion |
| **Application**      | Yes, see Application Form Kick-off Meeting |
| **List of Questions**| Yes, see Application Form Kick-off Meeting |
| **Documents to be submitted (per e-mail)** | simultaneously with the application:  
☐ Application form Kick-off Meeting  
☐ Briefing Document (approx. 10 pages) containing:  
• Project summary  
• Topics for the discussion  
• Background information |
| **Meeting Minutes**  | No |
| **Fees: AMGKostV/BGebV-MPG** | Yes (Fees paid by applicant) |
2. Procedure for Kick-off Meetings

The decision whether a consultation takes place in form of a Kick-off Meeting is made by the BfArM. Please note, that there is no legal entitlement to the service of a Kick-off Meeting.
A Kick-off Meeting needs to be applied for at the BfArM Innovation Office and is subject to fees.
Kick-off Meetings at the BfArM are face to face meetings.

The objective of a Kick-off Meeting is an informal exchange among experts from the BfArM and the applicant in order to discuss general questions related to regulatory aspects or present uncertainties regarding mandatory administrative procedural steps or required data in relation to the applicant's development project. Advice about specific aspects of individual development projects is outside the scope of a Kick-off Meeting; these specific aspects are covered by Scientific Advice procedures. BfArM neither provides the required development programme nor conducts a preliminary assessment of data in light of a forthcoming authorization procedure.

2.1 Application

When applying for a Kick-off Meeting, the following points should be considered:
A request is restricted to
- (academic) research institutions or
- Micro-, small- and medium-sized enterprises, start-ups
not familiar with regulatory issues and asking for guidance towards responsibilities and necessary further steps relevant for planning a clinical trial or a forthcoming marketing authorisation application

Furthermore, Kick-off Meetings are generally focused on products
- in initial phases of development (e.g. prior to the beginning of clinical trials)
- which are not yet approved/marketed in Germany/in the European Union (EU)
- which do not substantially coincide with products already available in Germany/EU in terms of composition, mode of action, intended use and/or manufacturing process
- for which delimitation matters (e.g. medicinal products/medical devices) and, in particular, regulatory processes and responsibilities are still unclear
- at the time of the application for a Kick-off Meeting by the Innovation Office, no Scientific or Regulatory Advice was given by the BfArM and/or the EMA

The request for a Kick-off Meeting needs to be made in writing using the application form available on the BfArM’s website.

The application should be sent to the e-mail-address indicated in section 3. It should be highlighted in the subject line that the submission concerns a request for a Kick-off Meeting.

An application consists of the following documents, appended to the e-mail:

**Application form**
Use of the application form is necessary to ensure that all relevant information for a valid request is provided at the time of initial submission.

The following points should be considered:

A. Applicant
   - Name and address of the applicant, including telephone number and e-mail address, as well as the billing address (if different)
   - Information about the project funding (if applicable)

B. Details about the Product
   - Information about the product
   - Information related to the classification (medicinal product or medical device), if already possible
   - Details about the composition or structure and mode of action/function or intended use of the product and information about the planned therapeutic or diagnostic use and route of administration (if already possible and applicable)
   - Information about previous or applied advice procedures
- Information about same or similar products/technologies already approved or marketed in Germany and/or EU
- Identification of clinical trials in which the applicant of the advice acts as sponsor, which are either on-going or applied for and are directly related to the development programme to be discussed
- Identification of the studies using EudraCT or EUDAID number

C. Meeting Details
- Information regarding the topics to be discussed during the Kick-off Meeting (multiple choice possible)
- Proposed meetings dates
- Preferred meeting language (German or English language)
- List of participants
  Prior to the meeting, BfArM expects a list of participants from the applicant. Positions/functions of the individual attendees should be listed. If the applicant makes changes to the list of participants during the planning phase, this should be communicated to the Innovation Office. In this context it should be highlighted that the number of participants should be limited. A group size of up to maximally 7 persons should not be exceeded by the applicant.

D. Confirmation regarding payment of fees

For a valid application confirmation must be given by marking the respective box with a cross.

**Briefing Document (Project Summary)**

The application form has to be supplemented by a briefing document (project summary) that introduces the product and provides necessary background information about the development project, including information on the current state of development, and the topic(s) for discussion (max. 10 pages).

The documentation should be submitted as PDF-file simultaneously with the application form electronically to the e-mail address indicated in section 3.
2.2 Meeting Preparation

New requests are being validated regarding form and content. Insufficient information or the lack of meeting the prerequisites for the request indicated in section 2.1 may lead to rejection of the application. Following validation of the request the BfArM decides whether a Kick-off Meeting will be arranged; the applicant will be informed whether the application will be accepted. Advice on specific aspects of individual development projects is not in the scope of a Kick-off Meeting. However, if the prerequisites for a Kick-off Meeting indicated in section 2.1 are not fulfilled and/or the need for subsequent Scientific Advice may be the result of a Kick-off Meeting, this advice needs to be applied for separately.

Scheduling
As a rule it will be possible to conduct a meeting within a timeframe of 6 weeks to 3 months; this, however, depends on the availability of the scientific units involved. The Innovation Office expects to receive the applicant’s presentation for the meeting at least 5 working days prior to the scheduled meeting date per e-mail.

Technical Aspects
Conference rooms are equipped with a multimedia projector, which can be hooked up to any laptop (VGA port). In case of other formats, suitable adapters are to be supplied by the applicant. If requested, BfArM can provide a laptop; however, this should be communicated to BfArM in advance.

2.3 Conduction of the meeting

A Kick-off Meeting is primarily a face to face meeting at the BfArM; in certain situations teleconferences are provided. As a rule, two hours are scheduled for meetings. The meeting is chaired by the BfArM. Following greetings and introduction of the participants, the applicant should start with a presentation of the project (20-30 minutes). This is followed by an informal discussion about general aspects regarding possible or necessary regulatory steps based on the project presentation and submitted questions.
2.4 Fees

The Institute's cost centre sends out an invoice after the advice procedure has been completed. The costs depend on the actual BfArM resources involved (human and other). The fees will be determined in accordance with the AMG-Fee or MPG-Fee Ordinances and can amount up to 10,000 €; the fees for a Kick-off Meeting may usually not exceed an amount of 2,000 €.

In case of withdrawal of the application or rejection of the application after initiation of processing fees will be charged in accordance with the AMG- and MPG-Fee Ordinances.

3. Contact

Bundesinstitut für Arzneimittel und Medizinprodukte (BfArM)
Unit "Advice, Innovation Office, Expert Panels"
Kurt-Georg-Kiesinger-Allee 3

D - 53175 Bonn

For electronic submission the following address is to be contacted:
E-Mail: innovation@bfarm.de

In case of questions related to Kick-off Meeting procedures the following contact is provided:

E-Mail: innovation@bfarm.de
Tel.: +49 (0) 228 99 307-4053

Depending on the type of question (content or scheduling), it is further suggested to contact the person listed on the initial receipt.